SEP 2 4 2001

K 012190
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## 510(k) SUMMARY

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| **NAME OF FIRM:** | Advanced Orthopaedic Solutions |
| **510(k) CONTACT PERSON:** | Gary Sohngen<br>President |
| **TRADE NAME:** | AOS Modular Femoral Nail |
| **COMMON NAME:** | Intramedullary Fixation Rod |
| **CLASSIFICATION:** | 888.3020 Intramedullary Fixation Rod. |
| **DEVICE CODE:** | HSB |
| **SUBSTANTIALLY EQUIVALENT DEVICE:** | Biomet, Uniflex Nail; DePuy Ace, TTC Fusion Nail; OrthoMatrix, Magellan I.M. Nail System |

**INTENDED USE:**

The AOS Modular Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following.

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with severe comminution and intra articular extension
- Ipsilateral femur fractures
- Bone lengthening
- Fractures proximal to a total knee arthroplasty or prothesis
- Fractures distal to a hip joint
- Nonunions and malunions
- Fractures resulting from osteoporosis

The AOS Femoral Modular Nail is also indicated for use in fusion of the knee and in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia.

**DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The Advanced Orthopaedic Solutions (AOS) Modular Femoral Nail is a titanium alloy modular nail consisting of a elongated nail body with a chamber at the proximal end that is designed to receive an insert with various screw hole configurations (antegrade, reconstruction, retrograde, dynamization, TTC fusion, etc.). A locking ring engages into the chamber to secure and retain the insert into the chamber. Additionally, there is an endcap that is threaded into the proximal end

of the nail to preload the locking ring to prevent loosening. The endcap also prevents the ingrowth of tissue into the proximal threads. The screw holes in the insert are designed to receive 6.5mm screws (antegrade, retrograde and TTC fusion) and 6.5mm and 4.5mm screws (reconstruction). The nail is cannulated through it entire length with the distal end of the nail containing three screw holes designed to receive 4.5mm screws. Nails of 30cm and longer have a radius to accommodate the anatomy of the femur

The overall diameter of the proximal chamber is 13mm regardless of the diameter of the nail and the working length diameters ranges from 9mm to 13mm. The nail is produced in lengths of 15cm to 50cm.

The inserts are identical overall dimensions but contain various screw hole configurations. The antegrade insert has one screw hole angled at 45°, the reconstruction insert has two holes that are also angled 45° into the femoral head, The retrograde/supracondylar insert has on cross locking hole and one slot and the TTC fusion insert had three cross locking holes.

The AOS Femoral Modular Nail was shown to be substantially equivalent to the following devices.

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| Biomet Uniflex Nail | K982953 |
| OrthoMatrix Magellan I.M. Intramedullary Nail | K971135 |
| DePuy ACE ACE TTC Fusion Nail | K003797 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2001

Mr. Gary Sohngen
President
Advanced Orthopaedic Solutions
333 West 6th Street, Suite 202
San Pedro, California 90731

Re: K012190
Trade/Device Name: AOS Modular Femoral Nail
Regulation Number: 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: July 12, 2001
Received: July 13, 2001

Dear Mr. Sohngen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph., M.D.
Director,
Division of General
Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K012190

Device Name: **Advanced Orthopaedic Solutions Modular Femoral Nail**

Indications for Use:

The AOS Modular Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following.

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
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- Fractures resulting from osteoporosis

The AOS Femoral Modular Nail is also indicated for use in fusion of the knee and in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012190